The Effect of Oral Nutritional Supplements on Muscle Strength in Older Hip Fracture Patients at Nutritional Risk (NUTRI-MUSCLES)

A Randomised Feasibility Trial for an Open-Labelled Parallel Randomised Control Trial

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Background
Malnutrition and dehydration are prevalent issues among older patients with hip fractures and may increase the risk of adverse outcomes. Nutritional support is therefore recommended to continue after hospitalisation to improve recovery.

Objective
To assess the feasibility and completeness of planned study methods, including recruitment and retention rate in the NUTRI-MUSCLES trial.

Methods
The NUTRI-MUSCLES trial included patients ≥ 65 years old at nutritional risk admitted with a hip fracture. Participants were randomised to receive an oral nutritional supplementation (ONS) twice a day for 12 weeks after discharge (intervention) or standard care (control) (Figure 1). The primary outcome of this feasibility study was recruitment and retention rate. Secondary outcomes were compliance and completement of data collection for 30-seconds chair stand test, physical function, quality of life, blood samples, appetite, frailty, muscle strength and body composition in the definitive trial.

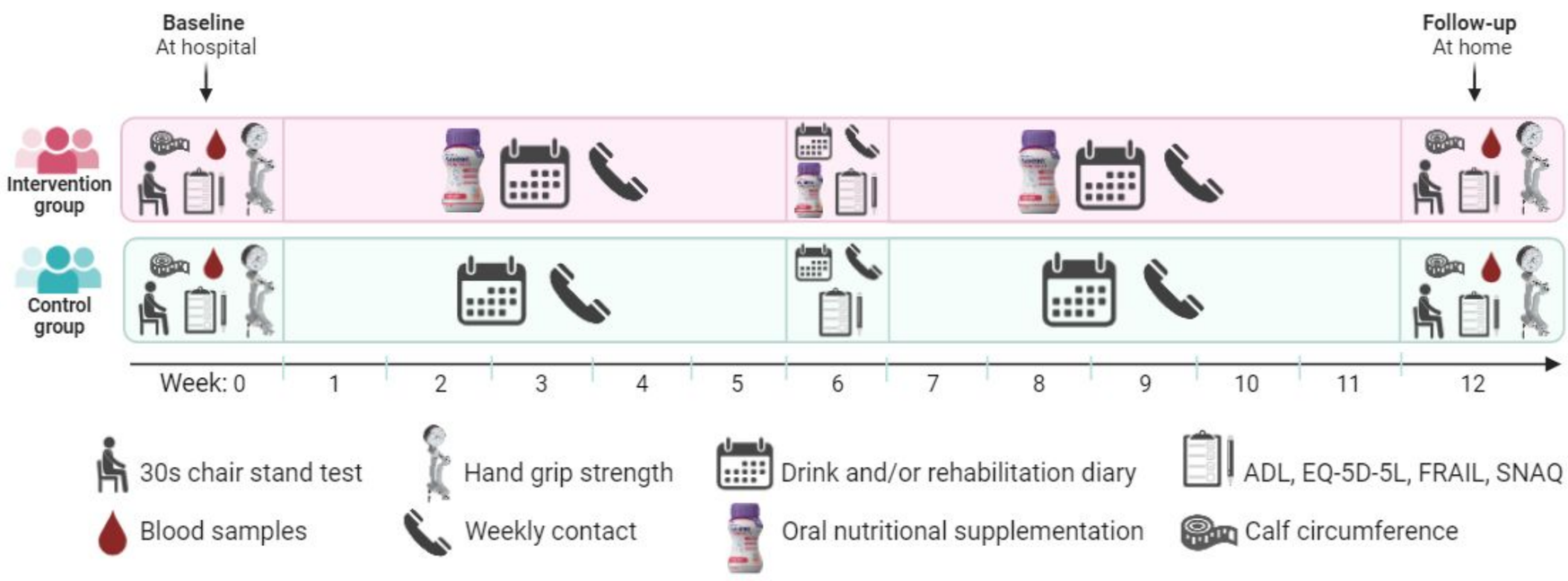

Figure 1: Trial overview and methods

Results
Out of 134 screened patients, 52 (39%) met the inclusion criteria (Figure 2). Of these, 21 (40%) accepted participation, 10 participants were allocated to the intervention group and 11 to the control group. Recruitment rate was **2.3** participants per week, and retention rate was **76%** (16/21). Reasons for withdrawal included regretting participation and feeling overwhelmed by current situation.

At baseline, **19%** (4/21) were able to perform 30s-CST using armrests, while all secondary outcome data collection was completed. At follow-up **94%** (15/16) could perform 30s-CST, of which 63 % did not use armrests. Blood samples were obtained for **81%** (13/16). Collection of remaining outcomes were **100%** successful. Compliance to ONS was **71%** estimated by counting cans and drinking diary.

Tabel 1: Baseline characteristics

	Intervention (n=10)	Control (n=11)
Age (years)	80 (76,86)	87 (75,91)
Female, n (%)	4 (40)	5 (45)
BMI	24.6 (24.0,24.6)	22.1 (21.0,24.5)
30s-CST modified, n (%)	3 (30)	1 (9)
Hand grip strength (kg)	18.7 (15.7,31.0)	23.7 (14.7,18.4)
Calf circumference (cm)	35.6 (33.5,36.5)	32.0 (31.0,35.0)
ADL (0-100)[a]	96 (79,100)	99 (82,100)
Frail, n (%)	4 (40)	5 (45)
Pre-frail, n (%)	6 (50)	6 (55)
EQ-5D-5L index[b]	0.410 (0.017,0.755)	0.178 (-0.074,0.467)
EQ-5D-5L VAS (0-100)	55 (40,78)	40 (30,60)
Vitamin D (nmol/L)	77 (57,95)	93 (76,122)
Osmolarity (mmol/L)	297 (295,298)	296 (294,298)
Dehydrated, n (%)	7 (70)	6 (55)
Omega-3 index (%)	6 (5,6)	6 (5,8)
SNAQ score < 14, n (%)	5 (50)	4 (36)

Data are presented as median (IQR) or as number of individuals (percentage). [a]Activites of daily living concerns time before fracture, all other variables are post fracture. [b]Quality of Life index score goes from -0.757 til 1. ADL, activities of daily living; BMI,body mass index; SNAQ, simplified nutritional appetite questionaire.

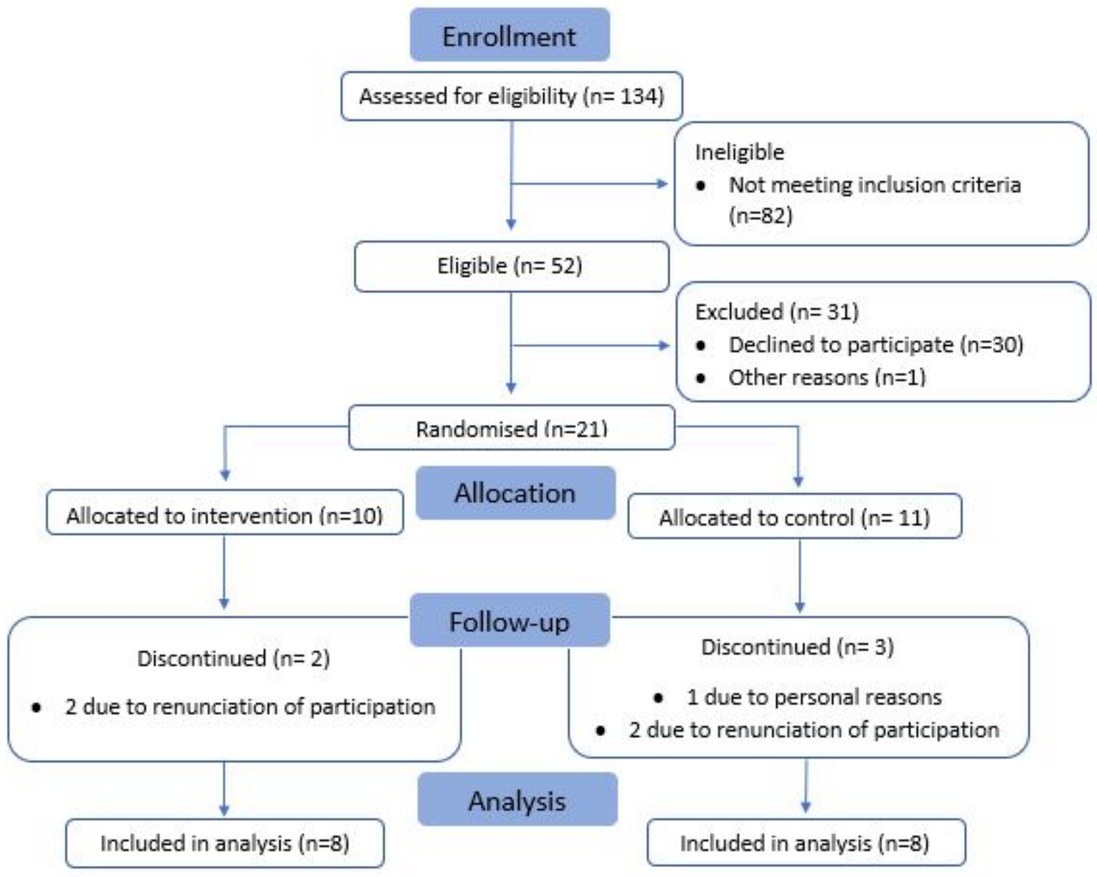

Figure 2: Flowchart of inclusion

Conclusion and perspectives
The NUTRI-MUSCLES trial demonstrated feasibility, achieving adequate recruitment and retention rate, and sufficient compliance. The applied methods proved effective, with > 80 % completeness for all outcomes except the 30s-CST at baseline. Baseline data reveal prevalent dehydration and decreased appetite among older hip fracture patients, indicating risk of weight loss (Table 1). These findings highlight the need for postoperative nutritional interventions in this patient group.

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